Contamination in Smooth Gel Breast Implant Placement: Testing a Funnel Versus Digital Insertion Technique in a Cadaver Model FREE

Hunter R. Moyer, Bahair Ghazi, Neil Saunders, Albert Losken

Author Notes

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Background: Overt infection and biofilm formation resulting from breast augmentation are rare but serious problems that can lead to contracture and a need for revision surgery. The Keller Funnel is a medical device composed of a rip-stop nylon sleeve with a hydrophilic inner coating. One claim of the funnel is that it facilitates a "no touch" technique, thereby limiting contamination. To date, there are no data to support this claim.

Objectives: The authors evaluate skin and breast parenchyma contamination with standard implantation techniques and the Keller funnel.

Methods: Insertion techniques were tested in two fresh cadavers. Smooth, round, moderate-plus silicone gel implants were placed for each experiment. To quantify the amount of skin contamination, a 2% w/v fluorescein paste was painted onto the cadaver thorax. After implantation, the implants were soaked in 250 mL of sterile water, and the fluorescence emission of the resulting solution was measured with an ultraviolet-visible spectrophotometer. To qualify the potential contamination from breast parenchyma, the cadaver breast tissue was swabbed with methicillin-sensitive *Staphylococcus aureus*, and the implant surfaces were cultured postimplantation.

Results: The funnel resulted in a 27-fold decrease in skin contact for all smooth gel implants ($P = .00059$). The amount of skin contact and potential contamination increased incrementally with increasing implant volume when either the funnel or digital implantation techniques were used. Bacterial contamination from breast parenchyma was two times more likely with the standard digital insertion technique ($P = .06$).

Conclusions: The Keller funnel appears to significantly reduce the amount of skin contact and potential parenchyma contamination.

Keywords: Keller, funnel, no touch, breast surgery, contamination

Topic: biofilms, cadaver, contracture, fluorescein, fluorescence, gel, nylons, repeat surgery, silicone gels, infections, breast implants, skin, chest, augmentation mammoplasty, breast surgery, breast tissue, medical devices, water, sterile, methicillin-susceptible staphylococcus aureus, parenchyma, touch sensation, implants, paste

Subject: Breast Surgery

Over four million women worldwide have received prosthetic breast implants for aesthetic and reconstructive purposes. Implants are widely considered safe, but they are not without local complications (such as hematoma and infection) and global complications (such as capsular contracture [CC] and size dissatisfaction). In our practice, patients are counseled that roughly one out of six women will require reoperation in the first year alone due to complications.[1]

Clinically-evident postoperative infection is reported to occur in 1% to 6% of cases in most large series[2-4]; however, complications related to it are serious. Infection is a pervasive problem; it often requires antibiotics and may necessitate additional surgery. Even after the initial insult is treated, the long-term complication of CC likely occurs at an increased frequency.[5]

CC is the leading cause of revisional breast surgery and occurs in anywhere from 5% to 74% of implantations.[3,6-16] Despite significant research efforts, contracture remains the most vexing complication for patients and surgeons. Multiple factors likely cause contracture, with infection being a significant contributor. In support of this, Dobke et al[17] detected bacteria on 76% of contracted implants, and Pajkos et al[18] reported that

89% of contracted capsules were culture positive. Recent research into biofilms confirm these results by projecting a fourfold increase in contracture in relation to subclinical infections.[5] Surgeons attempt to limit infection via antibiotic irrigation of the pocket, through placement of implants in the submuscular plane, or by placing Silastic drapes to limit skin contact.

The Keller Funnel (Keller Medica, Stuart, Florida) is a new US Food and Drug Administration (FDA) Class I device composed of a rip-stop nylon sleeve with a hydrophilic inner coating. One claim of the manufacturer is that the funnel allows the surgeon to employ a "no touch" technique while inserting a breast implant. To date, no in vitro or in vivo data support this claim, nor are there any quantifiable data in the literature defining the amount of skin contact during the digital and funnel implantation techniques. The aim of this study was to qualify and quantify the amount of skin contact and potential bacterial contamination that occurs during breast implantation techniques.

Methods

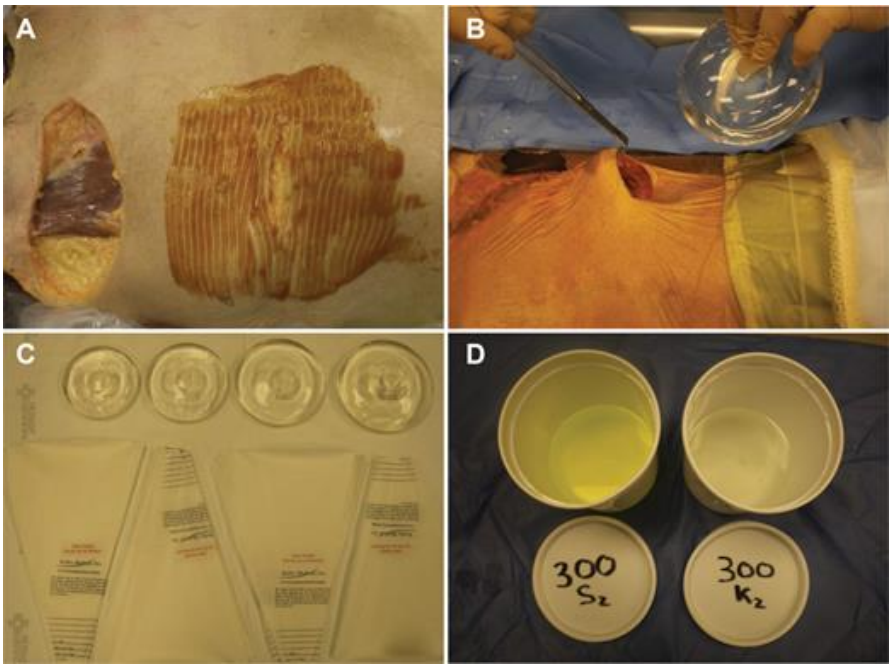
Implant Devices

Smooth, round, moderate-plus silicone gel implants (Mentor Corporation, Santa Barbara, California) were selected for this study in sizes of 300, 375, 500, and 600 cc. The implants were cleaned and sterilized between each experiment. For the bacterial contamination experiment, the implants were soaked in 50% ethanol for five minutes between each implantation. For the fluorescein dye experiment, the implants were rinsed with 50% ethanol and towel dried.

Cadaver Model

Two freshly embalmed cadavers were used for the experiments. Five-centimeter incisions were made in each inframammary fold, and a standard subglandular breast pocket was dissected with sharp and blunt dissection. A large elliptical portion of soft tissue was removed inferior to the clavicle to gain easy access to the breast pocket. This opening was sufficiently large to allow for explantation of the implant without loss of surface-coated dye (Figure 1). Implantation was performed with a Keller Funnel cut to the appropriate tip diameter or via the standard two-hand digital technique. The surgical field, cadaver skin, instruments, and breast pocket were cleaned with 50% ethanol and towel-dried between each implantation experiment. Implantations were repeated in triplicate for each size of implant and for each implantation technique, and the experiments were repeated for a total of six.

Figure 1.



Cadaver implantation model. The inframammary skin surrounding the incision is painted with fluorescein paste. (A) Note the large subclavicular window to retrieve the implant. (B) The standard implantation technique for the parenchymal bacteria experiment. (C) Funnels and the four sizes of implants. (D) The resulting fluorescein solution after the standard and funnel implantations.

Fluorescein Preparation

Five grams of fluorescein powder (Sargent-Welch, Tonawanda, New York) was mixed with 250 mL of Aquasonic ultrasound gel (Parker Laboratories, Fairfield, New Jersey) to create a 2% w/v paste. For each trial, 5 mL of fluorescein paste was painted onto the skin in a large region surrounding the incision of the cadaver specimen. The paste was then combed to yield an even surface coating. After each implantation, the Mentor implants were soaked in 250 mL of sterile water in a 1-L specimen container for exactly five minutes. Implants were then removed, and 5 mL of the resulting solution was aspirated and placed into 15-mL conical tubes (BD Biosciences, Franklin Lakes, New Jersey) for storage.

Ultraviolet-Visible Spectrophotometry

The solution containing leached fluorescein dye from the implant surface was immediately transported to the Emory University Center for Systems Imaging. Half-milliliter samples from each specimen were transferred into wells of a 24-well tissue culture plate (BD Biosciences, Franklin Lakes, New Jersey). Fluorescent emissions were measured in each well with a Meastro 2 spectrophotometer (Cri, Cambridge, Massachusetts) with a blue lens measuring wavelengths between 500 and 720 nm. Emittance was calculated with Maestro EX 2.10 software (Cri).

Culture Preparation

Two vials of methicillin-sensitive *Staphylococcus aureus* (ATCC, Manassas, Virginia) were reconstituted with 1 mL of sterile water, and each vial was diluted into a 20-mL bottle of sterile water. Sterile tissue swabs were immersed into the bacterial broth and then used to paint the breast parenchyma within the inframammary incision. After implantation, the breast implant was removed from the subclavicular window, and culture swabs

were passed over all surfaces of the implant. Cultures were sent to an independent culture lab (Antech Diagnostics, Smyrna, Georgia) for processing. Between each implantation, the breast pocket, skin, and incision were sterilized with 2% chlorhexidine gluconate (ChloraPrep, El Paso, Texas). A positive swab and a negative control swab were analyzed along with a test culture between each set of experiments to ensure sterility.

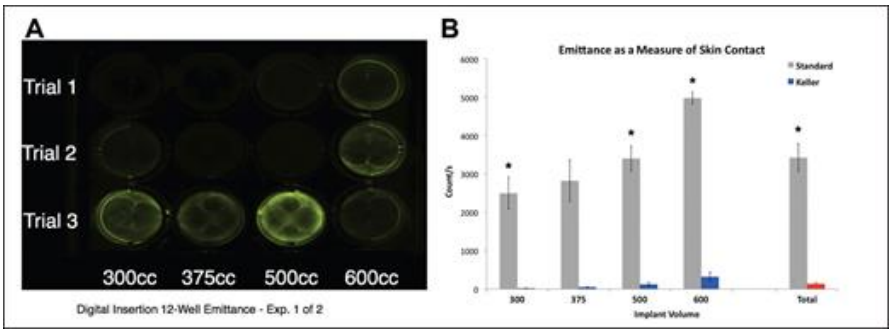
Cultures were reported as bacterial identification, amount of growth, and sensitivities. The amount of growth was quantified as *none, scant, light, moderate*, and *heavy*, and a numeric scale was applied to each amount as follows: none = zero, scant = one, light = two, moderate = three, and heavy = four.

Results

Fluorescein emission was detected by the spectrophotometer from all explanted implants regardless of technique. The amount of emission was so low in the implants inserted with the funnel that the length of time of detection with the ultraviolet-visible spectrophotometer had to be increased. All data therefore are reported in counts per second to appropriately compare groups.

Of the 24 implantations performed with digital insertion, the average emittance of the fluorescein dye/water solution was 3423.9 counts per second. The emittance—and, therefore, the amount of skin contact—increased proportionally with the volume of the implant in a dose-dependent manner (Figure 2). The averages for the 300-, 375-, 500-, and 600-cc implants were 2496.6, 2820.8, 3402.8, and 4975.3, respectively.

Figure 2.



Results from the fluorescein skin contact experiment. (A) Twenty-four-well plate loaded into the spectrophotometer. One well holds a 0.5-mL specimen from each trial and each implant size. Emittance was measured as counts per second. (B) The amount of skin contact as a function of fluorescein concentration for each technique and volume of implant.

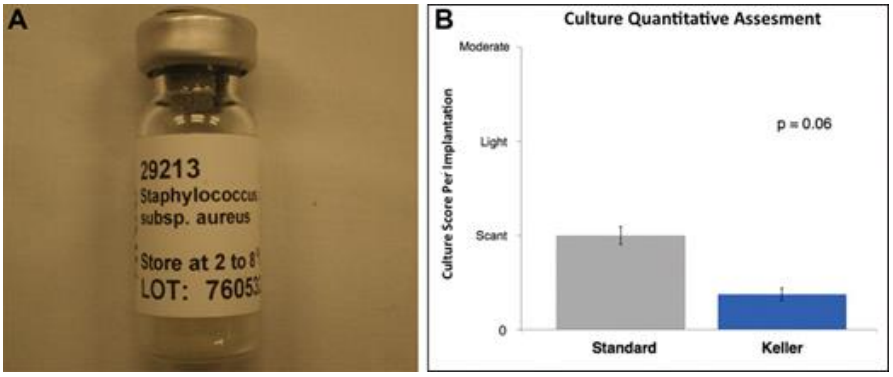
The average emittance for the 24 implantations utilizing the funnel was 128.36 counts per second (P = .00059).Again, a proportional increase in skin contact was evident with ever-increasing implant volume. The averages for the 300-, 375-, 500-, and 600-cc implants were 19.499, 50.581, 123.05, and 320.33, respectively. The reduction in skin contact for each implant volume was statistically significant except with the 375-cc implants, which showed a trend toward significance (P = .0354, P = .063, P = .0021, and P = .00001 for 300-, 375-, 500-, and 600-cc implants, respectively).

In total, implants inserted with the funnel demonstrated a 27-fold decrease in skin contact compared to digital insertion. The reduction in contact was most pronounced in smaller implants, with the 300-cc implants experiencing a 128-fold reduction. Each incremental increase by roughly 100 cc decreased the reduction in skin contact by half: a 55-fold decrease for the 375-cc implant, 28-fold decrease for the 500-cc implant, and 15-fold decrease for the 600-cc implant.

Bacterial transfer from the breast parenchyma to the implant shell was detected in 62.5% of the standard implantations and 37.5% of the funnel-propelled implants. All positive cultures

grew MSSA except for two cultures that also grew a nonpathogenic bacillus strain. Grading the amount of contamination gave an average score of 1.0 per digital insertion, which is equivalent to scant growth cultured from each implantation. Implants inserted with the funnel graded at 0.375 per implantation, a number one-third of the way between no growth and scant growth per implant (Figure 3, $P = .06$). No correlation was noted for either technique with regard to the size of the implant and the amount of bacterial transfer.

Figure 3.



Results from the bacterial contamination experiment. (A) *Staphylococcus aureus* was painted onto the breast parenchyma within the wound. (B) Implantation experiments showed, on average, scant transmission onto the implant with the standard technique and less with the funnel technique.

Discussion

Silicone gel breast implantation has been a dynamic process since its inception in 1963. Fourth-generation silicone gel implants are currently on the market, with each generation improving upon the feel and shape of the device as well as the durability and reactivity of the shell. Surgical techniques have also changed over the decades to include the transaxillary, periareolar, and umbilical approaches (saline implants only). Finally, implantation techniques have recently been scrutinized due to a better understanding of bioflims and potential causes

of CC. Techniques employed by surgeons to address contamination include placing Tegaderm (3M, St. Paul, Minnesota) over the nipple-areolar complexes, Ioban (3M) over the entire surgical field, irrigating vigorously with antibiotic solution, and changing gloves prior to implantation. Despite these best efforts, infection and contracture continue to cause significant morbidity after implantation.

The breast is not a sterile organ. The terminal ducts at the nipple and areola are colonized with endogenous flora, most often coagulase-negative *Staphylococcus* species.[19] These ducts run deep into the breast tissue and violation can lead to contamination. More important, a patient's skin may not be sterile at the time of implantation. Surgical preparation of the patient at the beginning of the operation does not guarantee a sterile field. As Saltzman et al showed, positive skin cultures after surgical preparation with povidone-iodine, DuraPrep, and ChloraPrep (both 3M) are 31%, 19% and 7%, respectively.[20] The most common bacteria cultured after surgical prep are coagulase negative *Staphylococcus* and *Propionibacterium*,[21] which, by no coincidence, are also the most common bacteria cultured from contracted capsules.[18]

Approximately two-thirds of infections occur in the immediate postoperative period and are likely due to a break in surgical technique or poor skin preparation.[19] Late infections can occur months to years after surgery and are caused by secondary bacteremia from a distant infection or declaration of a subclinical infection from the initial surgery. Recent investigations into biofilms have placed further importance on sterility at the initial surgery to prevent even late complications. As stated above, cultures taken of contracted capsules years after surgery most often grow *Staphylococcus epidermidis*, a known skin contaminant.[17,18] Management of these infected implants is controversial. A review of historical FDA-reported data shows that a majority (56.6%) of infected breast implants

were removed.[22] More recent reports discuss management with intravenous antibiotics, local wound care, and/or operative debridement with implant salvage.[23] No matter the treatment strategy, breast implant infections are a significant burden to the patient and the health care system.

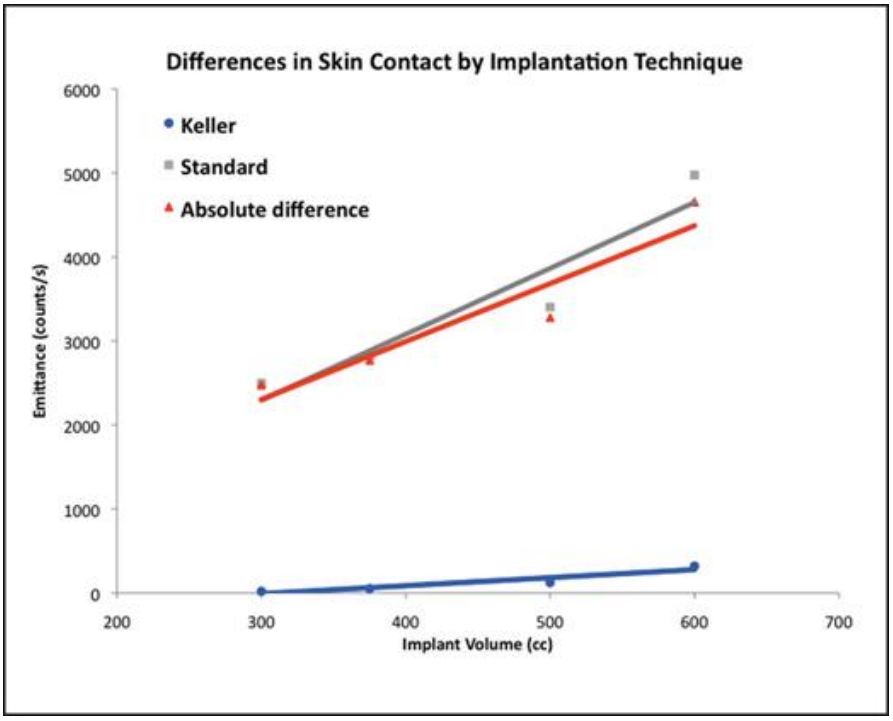
A true "no touch" technique would allow for placing a breast implant directly into the breast pocket without ever touching instruments, drapes, gloves, or the patient's skin and parenchyma. Even after meticulous surgical preparation, the skin and surgical field can remain contaminated; thus, placing Ioban, changing surgical gloves, or reprepping with a product that cannot completely rid the skin of bacteria is of little utility. Prophylactic cefazolin is not likely to help, as 30% to 80% of *S. epidermidis* cultured from patients' skin is methicillin resistant.[24-26]

The Keller Funnel is a device that claims to deliver a true "no touch" technique in implant placement, but the data from this study support the claim of a "minimal touch" technique. Using the funnel decreased the amount of skin contact 27-fold for all implants. The amount of direct parenchymal contamination was less than half the standard technique, a number that strongly trended toward significance.

We found an indirect relationship between percentage of reduction in skin contact and increasing implant volume. As the implant increased in volume by 100 cc, skin contact increased by 250% for the funnel and 125% for the standard technique. For both techniques, the implant surface contact area increased with increasing implant volume. In addition, the surgeon is required to cut a larger opening in the base of the funnel for larger implants, thereby augmenting the relative implant area and exposure. This appears to show that the funnel is less effective for larger implants; however, this is not the case. When examining the absolute difference in skin contact, it is clear that larger implants experience more contact, but the

percentage of decrease is less. As shown in Figure 4, the trend line depicting absolute difference in skin contact has an increasing slope as the implants increase in volume.

Figure 4.



This chart shows the differences in skin contact between the funnel and standard implantation techniques. Note that the red line depicting absolute reduction in skin contact has a positive slope.

Surgeons should heed several technical points when employing the funnel. To ensure sterility, the implant should soak in antibiotic solution in the original package. When ready to implant, the scrub nurse should pour the implant and solution directly into the funnel. The surgeon should then load the implant toward the tip of the funnel without allowing the device to protrude from the end, and the assistant should place a clean retractor into the pocket. The implant should then be propelled into the pocket, after ensuring that the funnel tip is inside the patient. Finally, the inside of the funnel should be used—rather than a finger—to push any portion of the implant that protrudes through the incision.

This study is limited in that it is an ex vivo cadaver model designed to mimic the breast implantation technique. The use of fluorescein dye is an indirect method to estimate the amount of skin contact; however, it has been validated in the literature.[27] We chose to use the inframammary incision, as it is the most common method of access, but different incisions may carry different rates of contact. Most important, we are speculating that contamination at the time of insertion can result in overt infection and CC. The literature and reasoning appear to support this theory, but the causes of CC have not been fully defined.[5]

Conclusions

The Keller Funnel appears to significantly reduce the amount of skin contact and potential parenchyma contamination during implantation of smooth gel breast implants in a cadaver model. Technical refinements when employing the funnel can result in a "minimal touch" technique that may lead to reduced infections and contracture.

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Disclosures

Dr. Losken is a consultant for Mentor Corporation and LifeCell Corporation. The other authors have nothing to disclose.

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